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CLAIMS

1. A system for graft delivery and anchoring within a recipient's blood vessel, comprising :

a) a graft shaped as a tube from biologically compatible material, its dimensions, in particular, the diameter and length, being defined by recipient's clinical state and results of angiographic measurements of its operated blood vessel, this graft of individual dimensions having a proximal end and a distal end:

b) a set of assembly units for assembling on its base at least one device for delivering a graft of individual dimensions within a blood vessel of a concrete recipient and for simultaneously anchoring this graft at both its ends to the blood vessel wall, this set containing:

i) at least one proximal head for holding a graft in the process of delivery within a blood vessel and for anchoring its proximal end to the wall of operated blood vessel, the proximal head having a through axial hole with an actuator therein, as well as means for holding the graft proximal end and means for anchoring this graft end to the blood vessel wall;

ii) at least one distal head for holding the graft in the process of its delivery within the blood vessel and for anchoring its distal end to the wall of operated blood vessel, the distal head having a through axial

hole with an actuator therein, as well as means for holding the graft distal end and means for anchoring this graft end to the blood vessel wall;

iii) at least one intermediate tube connecting said proximal and distal heads, this tube having rigidity in longitudinal direction and relative flexibility in lateral direction and having a through axial hole;

iv) at least one control means configured substantially as a control lever serving for controlling the process of inserting the graft delivery device within an operated blood vessel, as well as for controlling actuators and means of proximal and distal heads for holding and for anchoring the graft ends, whereby said proximal and distal graft ends are simultaneously secured to the wall of this blood vessel;

v) at least one intermediate tube connecting said distal head and control lever, this tube having rigidity in longitudinal direction and relative flexibility and having a through axial hole;

vi) at least one flexible control element passing via said through axial holes of proximal; distal head, intermediate and additional tube and operatively connecting said actuators of proximal and distal heads with the control lever.

whereby there is provided the delivery of a graft of individual dimensions in a required area of the blood vessel and fixation of both ends of this graft to the wall of said blood vessel.

2. A system according to claim 1, wherein said graft is formed as a tube from biologically compatible material, substantially from foam polytetrafluoroethylene – ePTFE (Teflon).

3. A system according to claim 2, wherein said graft is formed as a tube from biologically compatible material, substantially from foam polytetrafluoroethylene – ePTFE (Teflon) with an anti-thrombogenic, substantially metal coating at least on one its bloodstream facing surface.

4. A system according to claim 3, wherein said graft is formed as a tube from biologically compatible material, substantially from foam polytetrafluoroethylene – ePTFE (Teflon) with an anti-thrombogenic, substantially titanium coating, at least on one, bloodstream facing surface.

5. A system according to claim 1, wherein said graft of individual dimensions shaped as a tube from biologically compatible material is set on this intermediate tube of said graft delivery device and secured by its ends on said proximal and distal heads of this graft delivery device.

6. A system according to claim 1, wherein said set of assembly units for assembling on its base at least one device for delivering a graft of individual dimensions within a recipient's blood vessel and simultaneously anchoring this graft at both its ends to the blood vessel wall additionally contains:

vii) a vein filter mounted at the free end of said proximal head of the graft delivery device and serving for cleaning a blood vessel from emboli and cholesterol patches.

7. A system according to claim 1, wherein said proximal head contains:

a) a cylindrical stepped body with a through axial hole of variable section, this body having a central part with an outer diameter corresponding to the inner graft diameter, a proximal and distal part, said proximal part having an outer diameter smaller than the outer diameter of central part, and at its free end forms a bush with external thread, said distal part having a shank for securing said intermediate tube;

b) means for holding the graft proximal end shaped as valleys for fixing the graft end, said valleys being located on the end face of central part of said body, in the region of its stepped transition to proximal part, as well as a spring-loaded fixing bush with ridges on its end face opposite to said valleys, and this spring-loaded fixing bush is

disposed coaxially with the proximal part of said cylindrical stepped body to reciprocate towards the central part of this body;

c) means for securing a graft proximal end to a blood vessel wall via fastener means, substantially U-shaped staples located in radial slots on the end face of central part of said body, alternating with said valleys, these means configured as rotatable levers for radially extending said U-shaped staples, these levers being pivotally mounted by one their end in through longitudinal slots evenly arranged in said body proximal part, parallel to its through axial hole, and the rotatable levers are adapted to cooperate by the free end of their outer surface with the middle part of said U-shaped staples, and by its inner surface with said actuator of the proximal head;

d) a hold-down bush with a thread on its inner surface mounted on a thread bush of the free end of said body proximal part, coaxially with said spring-loaded fixing bush, the hold-down bush being reciprocable over the thread to adjust the force of tightening said spring-loaded fixing bush to said end face of the body central part;

e) an actuator configured as a cylinder with a through axial stepped hole and conical working surface mounted in the through axial hole of said cylindrical stepped body to reciprocate in this hole and periodically cooperate by its conical working surface with the inner surfaces of said rotatable levers for radially extending said U-shaped

staples, this actuator being rigidly secured on said flexible control element passing via said through axial holes of proximal, distal head, intermediate and additional tubes and operatively connecting said actuators of proximal and distal head with said control lever.

8. A system according to claim 7, wherein said valleys for fixating the graft proximal end are substantially disposed on the edge of end face of said central part of the body, in the region of its stepped transition to the proximal part of this body.

9. A system according to claim 7, wherein each of said radial slots for locating fastener means, substantially U-shaped staples, terminates in a means for setting apart the ends of these staples configured as two curved ducts disposed in said end face of the central part of said body symmetrically with its radial axis and sufficiently close to one another, the curved ducts diverging from one another in direction from the through axial hole of said body to its outer surface, each U-shaped staple being disposed by its middle part within said through axial hole of the body, and by its free ends – in two said curved ducts, to extend these free ends in direction from the inside to the outside due to radial force applied to a U-shaped staple from within the body hole,

whereby the staple is withdrawn from said curved ducts, pierces the wall of the graft and of a corresponding blood vessel and comes out onto the outer surface of this blood vessel to bend thereon and thus fix the graft location relative to this blood vessel.

10. A system according to claims 7 and 9, wherein rotatable levers for radially extending said U-shaped staples pivotally secured by one its end in through longitudinal slots of the proximal part of said cylindrical stepped body and adapted to cooperate by the free end of its outer surface with the middle part of said U-shaped staples, and by its inner surface – with said actuator of the proximal part, have at least two different lengths, whereby the number of levers that may be located, and hence the number of U-shaped staples extended by these levers increases.

11. A system according to claim 7, wherein said spring-loaded fixing bush located coaxially with the proximal part of said cylindrical stepped body to reciprocate towards the central part of this body is provided with ridges on its end face presented to the end face of this central part of the body, said ridges being opposite to said valleys and said means for setting apart the ends of said U-shaped staples and serve for fixing respectively the end of graft and U-shaped staples in the process of graft delivery.

12. A system according to claim 1, wherein said distal head contains :

a) a cylindrical stepped body with a through axial hole of variable section, this body having a central part with an outer diameter corresponding to the inner diameter of the graft, a proximal and distal part, said distal part having an outer diameter smaller than the outer diameter of the central part, and at its free end forms a bush with external thread, said proximal part having a shank for securing said intermediate tube;

b) means for holding the graft distal end, said means containing valleys for fixing the graft end located on the end face of said body central part, in the region of its stepped transition to the distal part, as well as a spring-loaded fixing bush with ridges on its end face opposite to said valleys, this spring-loaded fixing bush being disposed coaxially with the distal part of said cylindrical stepped body, to reciprocate in direction to the body central part;

c) means for securing the graft distal end to a blood vessel wall via fastener means, substantially U-shaped staples located in radial slots on the end face of said body central part, alternating with said valleys, these means containing rotatable levers for radially extending U-shaped staples, these levers being pivotally secured by one its end in through longitudinal slots evenly arranged in the distal part of the body, parallel with its axial hole, the rotatable levers adapted to

cooperate by the free end of its outer surface with the middle part of said U-shaped staples, and by its inner surface with said distal head actuator ;

d) a hold-down bush with a thread on its inner surface set on a thread bush of the free end of the distal part of this body, coaxially with said spring-loaded fixing bush, the hold-down bush adapted to reciprocate along the thread to adjust the force of tightening said spring-loaded fixing bush to said end face of said body central part;

e) an actuator configured as a cylinder with a through axial stepped hole and conical working surface, located in the through axial hole of said cylindrical stepped body to reciprocate in this hole and periodically cooperate by its conical working surface with inner surfaces of said rotatable levers for radially extending said U-shaped staples, this actuator adapted to reciprocate on said flexible control element passing via said through axial holes of proximal, distal head, intermediate and additional tube and operatively connecting said actuators of proximal and distal head with the control lever.

13. A system according to claim 12, wherein said valleys for fixing the graft distal end are located substantially on the edge of said end face of central part, in the region of its stepped transition to the distal part of this body.

14. A system according to claim 12, wherein each of said radial slots for locating fastener means, substantially U-shaped staples, terminates in a means for setting apart the ends of these staples, said means containing two curved ducts disposed in said end face of the central part of said body symmetrically with its radial axis and sufficiently close to one another, the curved ducts diverging from one another in direction from the through axial hole of said body, each U-shaped staple is disposed by its middle part within said through axial hole, and by its free ends — in two said curved ducts to extend these free ends in direction from the inside to the outside due to radial force applied to the U-shaped staple from within the body hole,

whereby the staple is ejected from said curved ducts, pierces the wall of the graft and a corresponding blood vessel, and comes out onto the outer surface to bend thereon and thus fix the graft location relative to this blood vessel.

15. A system according to claim 12, wherein rotatable levers for radially extending said U-shaped staples pivotally secured by one its end in through longitudinal slots of the distal part of said cylindrical stepped body and adapted to cooperate by the free end of its outer surface with the middle part of said U-shaped staples, and by its inner surface with said actuator of the distal head, have at least two lengths.

whereby the number of levers that may be located, and hence, the number of U-shaped staples simultaneously extended by these levers is increases.

16. A system according to claims 12 and 14, wherein said spring-loaded fixing bush disposed coaxially with the distal part of said cylindrical stepped body to reciprocate in direction to the central part of said body is provided with ridges on its end face presented to the end face of this central part of said body, said ridges being opposite to said valleys and said means for setting apart the ends of said U-shaped staples and serve to fix respectively the end of graft and U-shaped staples in the process of graft delivery.

17. A system according to claim 1, wherein said at least one control lever serving to control the process of inserting a graft delivery device within an operated vessel, as well as to control the actuators of said proximal and distal head comprises:

a) a hollow body having a proximal end, distal end with a perpendicular slot and a longitudinal axial duct, wherefrom within the body, near its distal end there extend at an acute angle two additional ducts, all said ducts extending within said perpendicular slot;

b) a bush with a shank at its proximal end and with a through axial hole disposed at the proximal end of this body:

c) a spring-loaded pusher with a through axial hole and two longitudinal slots open to opposite sides, this spring-loaded pusher adapted to reciprocate within the longitudinal axial duct of the body, provided with a lock and operatively connected via an additional hold-down element with said actuator of the distal head;

d) a curved L-shaped lever pivotally secured by the middle of its short arm in said perpendicular slot of the body and provided with a first and second pivot pin at the ends of this short arm, the first pivot pin adjoining the long arm of said L-shaped lever being operatively connected with said spring-loaded pusher, whereas the second pivot pin is operatively connected with said at least one flexible control element passing via said through axial holes of the proximal, distal head, intermediate, additional tube and spring-loaded pusher and operatively connecting said actuators of the proximal and distal head with control lever.

18. A system according to claim 1, wherein said at least one flexible control element passing via said through axial holes of the proximal, distal head, intermediate, additional tube and and spring-loaded pusher

and operatively connecting said actuators of proximal and distal head with control lever is configured substantially as a wire.

19. A system according to claim 1, wherein said at least one flexible control element passing via said through axial holes of proximal, distal head, intermediate, additional tube and spring-loaded pusher and operatively connecting said actuators of the proximal and distal head with the control lever is configured as a thin cord.

20. A system according to claim 1, wherein said at least one control element passing via said through axial holes of the proximal, distal head, intermediate, additional tube and spring-loaded pusher and operatively connecting said actuators of the proximal and distal head with the control lever is shaped substantially as a plastic thread.

21. A system according to claim 17, wherein said additional hold-down element operatively connecting said spring-loaded pusher of the control lever with said actuator of the distal head is connected therewith by its corresponding ends and is shaped as a tube member, said tube member being rigid in longitudinal direction and relatively flexible in lateral direction, such as a plastic tube or flexible hollow shaft having a through axial hole for said flexible control element.

22. A method for graft delivery and anchoring within a recipient's blood vessel via the claimed system comprising the following successive steps:

a) defining individual dimensions of the delivered graft, such as the diameter and length of this graft according to clinical state of a recipient and results of angiographic dimensions of its operated blood vessel;

b) assembling on the basis of said set of assembly units at least one device for delivering a graft of individual dimensions within the recipient's blood vessel and simultaneously securing this graft on both its ends to the blood vessel wall, and to this end there are selected a proximal head and a distal head of a corresponding diameter, intermediate and additional tube of corresponding length, as well as a control lever and flexible control element and they are connected together in such a way that said flexible control element should pass via through axial holes of proximal, distal head, intermediate and additional tube and operatively connect said actuators of the proximal and distal head with said control lever;

c) providing the assembled device with a vein filter attached to the actuator of said proximal head on the side of its hold-down bush;

d) setting the delivered graft outside the intermediate tube and fixing its ends in said proximal and distal head;

e) inserting the system thus assembled, held by the control lever, within the recipient's blood vessel and X-ray checking of the location of

this system relative to the given blood vessel, the vein filter mounted at the free end of said system trapping emboli and cholesterol patches encountered on its way:

f) pressing, when the system has reached the necessary position, said L-shaped lever of the control lever, whereby the actuators of said proximal and distal head move towards one another to eject in radial direction said U-shaped staples of both heads and suture the graft at both its sides, and the ejected U-shaped staples loosen by their middles the ridges of said spring-loaded fixing bushes of said proximal and distal head, moving these bushes aside and releasing graft ends clamped in said heads;

g) withdrawing the system from the graft sutured at both its ends to a blood vessel as well as from said blood vessel, the vein filter pressed by its end to the end of said hold-down bush of the proximal head is locked by this bush, and its contents – sealed in this filter.

h) utilizing the withdrawn single-use system and checking the operation results.